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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,555	10/31/2003	Roland Christof Hutter	21686-US	9951

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Roche Molecular Systems, Inc.
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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
08/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,555	HUTTER ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07 July 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "said cuboid" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaami (US 20010016321).

With respect to claim 9, Tanaami discloses a reaction vessel for processing a biological sample. The reaction vessel comprises a tubular body (Figure 5:12) having a bottom wall, an upper opening and sidewalls. The bottom walls and sidewalls form a straight tubular chamber for receiving a liquid and for interacting with a pipetting tip. A chip shaped carrier (Figure 5:16) having an active surface formed by a plurality of biopolymers (Figure 5:CL21-CL23) is located on the inner surface of the tubular sidewall. This is disclosed in paragraphs [0024]-[0026].

With respect to claim 10, Tanaami discloses the reaction vessel in claim 9 wherein the tubular body is configured and dimensioned such that, when the chip shaped carrier is contacted with a liquid, an air space exists between the free surface of the liquid and the upper opening. Although Tanaami does not clearly describe these limitations, the disclosed device is configured and dimensioned in such a way that it is capable of fulfilling these requirements. This is apparent from Figure 5.

With respect to claim 11, Tanaami discloses the reaction vessel in claim 9 wherein the chip shaped carrier is located at a predetermined distance fro the bottom wall and from the upper opening of the tubular body.

With respect to claims 12 and 13, Tanaami discloses the reaction vessel in claim 9 wherein the chip shaped carrier is transparent. In paragraph [0030], Tanaami teaches that the biopolymers immobilized upon the carrier are optically evaluated using a light source and a detector. Figure 5 indicates that the excitation light and emission light are moved through the body of the carrier, as well as through the sidewall of the tubular chamber.

With respect to claims 22 and 23, Tanaami discloses the reaction vessel in claim 9 wherein the vessel further comprises a cap (figure 5:13) for removably closing the opening. The rubber plug cap is configured and dimensioned such that a part thereof may cooperate with the gripper of a transport mechanism.

With respect to claim 24, Tanaami discloses the reaction vessel in claim 9. The only opening disclosed by Tanaami is the upper opening of the tubular body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 17, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) as applied to claim 9.

Tanaami discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not provide specific dimensions describing the volume of the reaction chamber or the shape of the carrier chip. Regardless, it would have been obvious to ensure that the chamber had a width of at least 1.5 mm and an inner volume of 10-800 microliters if it was determined that these dimensions produced the most effective results. Reaction chamber side lengths are considered result effective variables that are optimized through routine experimentation. Furthermore, it would have been obvious to ensure that the carrier chip had a side length between 2 to 10 mm. A chip of these dimensions would be large enough to be easily micromachined using known techniques, but small enough to fit within a common test tube. At the time of the invention, it would have been apparent to fashion the reaction chamber disclosed by Tanaami according to the specifications presented in claims 17, 18, 20 and 21 if it was determined that these measurements allowed the device to function at an optimum level.

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lary (US 4845025).

Tanaami discloses the reaction vessel as previously described above, however, does not expressly indicate that the vessel is in communication with a vessel holder capable of moving along a predetermined elliptical trajectory.

Lary discloses a system from processing a test tube (Figure 15:24) in which a reaction vessel is coupled to a vessel holder in the form of a mixing arm (Figure 15:52). Figures 15 and 16 and column 7, line 59 to column 8, line 13 state that the mixing arm is moved along a predetermined elliptical trajectory for causing mixing of fluids within the vessel.

Lehmann and Lary are analogous art because they are from the same field of endeavor regarding reaction vessels.

At the time of the invention, it would have been obvious to utilize a moving means such as described by Lary to influence mixing within the reaction vessel disclosed by Tanaami. It is well established in the art that mixing means are beneficial because they allow one to provide effective contact between the sample solution and the active surface of the chip shaped carrier. The specific mixing mechanism of Lary is advantageous because it is highly reproducible, inexpensive, and more reliable than other mixing devices that are based on liquid circulation via pumping.

3) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) in view of Lary (US 4845025) as applied to claim 5, and further in view of Frackleton (US 5133937).

Tanaami and Lary disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30)

that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

Tanaami, Lary and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to incorporate heat transfer elements in the system disclosed by Tanaami. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

4) Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) as applied to claim 9, and further in view of Frackleton (US 5133937).

Tanaami discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

At the time of the invention, it would have been obvious to ensure that the device disclosed by Tanaami was capable of interacting with various heat transfer elements. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature

sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

5) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaami (US 20010016321) as applied to claim 9, and further in view of Mochida (GB 2129551).

Tanaami discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly indicate that the sidewalls carry a barcode label.

Mochida discloses the use of immunoassay vessels (Figure 1:1) that utilize barcode labels (Figure 1:2) as a tracking mechanism. This is disclosed on page 3, lines 60-64.

Tanaami and Mochida are analogous art because they are from the same field of endeavor regarding biological analysis devices.

At the time of the invention, it would have been obvious to include a bar code label on the outer sidewalls of the reaction vessel disclosed by Tanaami. Bar codes are helpful in quickly sorting and tracking reaction vessels, and they can be used to immediately determine the identity of a specified reaction vessel in the presence of a plurality of otherwise identical reaction vessels, thus reducing confusion and the occurrence of mistakes.

Response to Arguments

In response to Applicant's amendments, all previously applied rejections under 35 U.S.C. 112 first paragraph have been withdrawn.

Applicant's arguments filed 07 July 2008 with respect to the 35 U.S.C. 103 rejections involving Lehmann, Sharpe and Combs have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of Tanaami and the combination of Tanaami and Lary.

The Tanaami reference discloses a tubular reaction chamber comprising a carrier chip attached to the inner surface of a sidewall.

The Lary reference clearly indicates that it is known in the art to move a reaction holder along a predetermined elliptical trajectory to encourage the mixing of fluids.

Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797